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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,704	08/16/2001	Giorgio Senaldi	A-695	3429

7590 02/25/2004

U.S. Patent Operations/KLN
AMGEN INC.
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EXAMINER

HUYNH, PHUONG N

ART UNIT PAPER NUMBER

1644

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,704	SENALDI, GIORGIO	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-66 and 81-95 is/are pending in the application.
- 4a) Of the above claim(s) 66 and 81-95 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 64 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 65 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 January 0816 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/10/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/03 has been entered.
2. Claims 64-66 and 81-95 are pending.
3. Newly submitted claims 66 and 81-95 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Group I (claim 64-65) is drawn to a method for increasing antigen-specific IgE production comprising administering **polypeptide** comprising SEQ ID NO: 2 or SEQ ID NO: 5, classified in Class 424, subclass 184.1. Group II (claim 66) is drawn to a method for detecting antigen-specific IgE production using **antibody** or fragment thereof that specifically binds to polypeptide of SEQ ID NO: 2 or 5 or a polypeptide encoded by nucleic acid sequence SEQ ID NO: 1, 2 or 4, classified in Class 435, subclass 7.1, and Group III (claims 81-95) is drawn to a method for treating IgE-related disease using purified **antibody** or fragment thereof that specifically binds to polypeptide of SEQ ID NO: 2 or 5 or a polypeptide encoded by nucleic acid sequence SEQ ID NO: 1, 2 or 4, classified in Class 424, subclass 130.1.

Inventions of Groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods for increasing antigen specific IgE production and the method of treating IgE related disease (Groups I and III) using distinct class of agents such as polypeptide and antibody versus the method of detecting (Group II) using antibody differ the with their respect to their process steps and endpoints. Therefore, they are patentably distinct. Further, the method of treating versus the method of diagnosing differs with respect to their Class and subclass. A search of Group I will not encompass Group II or III. A prior art search also requires a literature search. It

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is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention (method for increasing antigen-specific IgE production using the polypeptide comprising SEQ ID NO: 2), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 66, and 81-95 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 66 and 81-95 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
5. Claims 64-65 are being acted upon in this Office Action.
6. Claim 65 is objected to because SEQ ID NO: 2 is a polypeptide and NOT a nucleic acid sequence.
7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.
8. Claim 64 is allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

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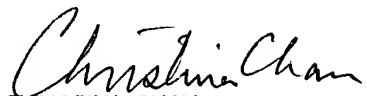
10. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

February 23, 2004


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600